

## REMARKS

### I. INTRODUCTION

In response to the Office Action dated March 22, 2004, claim 4 has been canceled, claims 1-2 and 5-6 have been amended, and new claims 7-8 have been added. Claims 1-2 and 5-8 remain in the application. Entry of these amendments, and reconsideration of the application, as amended, is requested.

### II. CLAIM AMENDMENTS

Applicants' attorney has made amendments to the claims as indicated above. These amendments were made solely for the purpose of clarifying the language of the claims, and do not introduce new matter. Support for the claim amendments can be found as follows.

The preamble of claim 1 has been amended to use the closed term "consisting of".

Claim 2 has been amended to introduce the limitations of canceled claim 4. In addition, claim 2 has been amended to clarify that the splice acceptor site of previous element (5) is contiguous with the Rev responsive element (RRE) of element (4) such that the claimed construct would not encompass one in which substantial intervening sequence (e.g., a tat or rev gene) would be present between the RRE and the splice acceptor site. This has been accomplished by presenting the two as a single element (4) consisting of an RRE that is contiguous with a splice acceptor site from the third exon of the HIV-1 tat and rev genes. This amendment is supported by the specification at page 5, line 22, and Figure 1.

Claims 5 and 6 have been amended merely to update the reference to previous claims.

New claim 7 is similar to claim 2, except that it references the construct of claim 1 as the first expression cassette.

New claim 8 is similar to claim 3, except that it references the composition of new claim 8.

Because none of these amendments introduces limitations that have not already been searched and examined together, entry of these amendments would not require further search by the Examiner. Entry of these amendments is respectfully requested.

### III. EXAMINER INTERVIEW

Applicants appreciate the helpful discussion and suggestions provided by the Examiner during a telephonic interview with Applicants undersigned representative on May 20, 2004. During this interview, discussion centered on the Kaul reference and a claim amendment strategy that would overcome this reference. Applicants have carefully considered the claim amendments presented herein and have proceeded with a good faith belief that these amendments will overcome the cited references without burdening the Examiner with new limitations to search. Should the Examiner disagree, the courtesy of a telephone call to Applicants undersigned representative would be most appreciated.

### IV. NON ART REJECTIONS

Applicants gratefully acknowledge the Examiner's withdrawal of the previous rejections raised under 35 U.S.C. §112, first and second paragraphs.

On page (5) of the Office Action, claims 1 and 2 were newly rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly lacked enabling support for a splice acceptor site that "is less efficient than the splice donor site". Also on page (5) of the Office Action, claims 1 and 2 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This latter rejection was based on the term "less efficient", which was regarded as indefinite. Applicants have amended claims 1 and 2 to delete the phrase "wherein the splice acceptor site is less efficient than the splice donor site", rendering these rejections moot.

### V. PRIOR ART REJECTIONS

Applicants gratefully acknowledge the Examiner's withdrawal of the previous rejection of claims 1 and 2 raised under 35 U.S.C. §102(b) as anticipated by Yu (J. Virology 1996).

On page (2) of the Office Action, claims 1, 3 and 5 were rejected under 35 U.S.C. §102(a) or 102(e) as allegedly anticipated by Carrano (U.S. Patent No. 5,739,118). On page (4) of the Office Action, claims 1-6 were rejected under 35 U.S.C. §102(a) as allegedly anticipated by Kaul (Virology, September 1998). The amendments to the claims render these rejections moot.

Moreover, the cited references do not provide any suggestion or motivation to modify their teachings to arrive at the claimed invention. The cited references are directed to constructs for use in gene delivery, which uses require additional elements not appropriate for or applicable to Applicant's claimed invention. The cited references teach strategies for inducible expression or elimination of viral particles to achieve safety for therapeutic applications.

In contrast, the claimed invention is directed to constructs useful for selecting cells that are suitable as packaging cells. This is accomplished through strategic placement of splice control elements, which allows for expression of a downstream selectable marker gene in the basal state and of the upstream gag/pol genes only upon induction. This arrangement permits selection of cells that express gag and pol without expression of products of the gag and pol genes, which can be toxic. As discussed at page 3 of the specification, the use of less efficient splice sites allows for more efficient expression from unspliced transcripts by the Rev-RRE system.

## VI. CONCLUSION

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

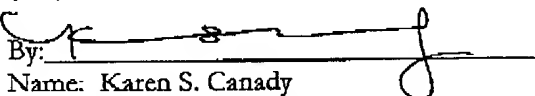
Respectfully submitted,

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